REMARKS

Claims 8-15 are currently pending. Claims 8, 9, 12 and 13 are currently amended. Support for these amendments, can be found, for example, on page 2, lines 3-7 and page 5, lines 1-5 of the application as filed. Claim 15 is newly added and is directed to a material for cartilage-like material substitution, comprising a fibre-reinforced polymerized hydrogel. The polymerized hydrogel contains 10-70% (m/m) swellable fibres (based on the dry matter) and the length of the fibres is at least a millimeter. Additionally, 1-5% (m/m) (based on the dry matter) of a substance that contains ionized groups has been added to said polymerized hydrogel and the swellable fibres comprise at least one monomer solution.

Amended claim 8 is directed to a material for cartilage-like material substitution, comprising a fibre-reinforced polymerized hydrogel. The polymerized hydrogel contains 10-70% (m/m) swellable fibres (based on the dry matter) and the length of the fibres is at least a millimeter. Additionally, 1-5% (m/m) (based on the dry matter) of a substance that contains ionized groups has been added to said polymerized hydrogel and the swellable fibres have sucked up at least one monomer solution prior to polymerization of the hydrogel.

In view of the claim amendments and following remarks, removal of the rejection and allowance of claims 8-15 are respectfully requested.

Claim Objections

Claims 12 and 13 are objected to because they appear "to be missing words". Claims 12 and 13 are currently amended to address these claim objections. In view of the present claim amendments, removal of the objection of claims 12 and 13 is respectfully requested.

Claim Rejections Under 35 U.S.C. §103

Claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge et al. (previously cited) in view of Slivka et al. (Tissue Engineering 2001 7:767-780), Pissis et al. (previously cited) and Young et al. (previously cited).

Claims 8 and 10-l1 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Slivka et al., Pissis et al. and Young et al. as applied to claims 8-9 and 12-14 above, and further in view of Kou et al. (previously cited).

Applicants respectfully traverse these rejections. The recently revised Examiner guidelines for assessing obviousness set forth detailed requirements based on asserted rationales for obviousness. The Rationales To Support Rejections Under 35 U.S.C. §103 provide the following possible rationales:

> (A) Combining prior art elements according to known methods to yield predictable results;
>
> (B) Simple substitution of one known element for another to obtain predictable results;
>
> (C) Use of known technique to improve similar devices (methods or products) in the same way;
>
> (D) Applying a known technique to a known device (method or product) ready for improvement to yield predictable results;
>
> (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
>
> (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; and
>
> (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

See MPEP 8th Edition, rev. 6, §2141.

Applicants proceed with the understanding that this rejection conforms to rationale G quoted above. The MPEP further sets forth the requirements for an obviousness rejection under this rationale:

> To reject a claim based on [rationale G], Office personnel must resolve the Graham factual inquiries. Then, Office personnel must articulate the following:

> (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
>
> (2) a finding that there was reasonable expectation of success; and
>
> (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.
>
> The rationale to support a conclusion that the claim would have been obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360, 80 USPQ2d 1641, 1645 (Fed. Cir. 2006). **If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.** [emphasis added]

See MPEP 8th Edition, rev 6, §2143

In *KSR*, the Supreme Court did not eliminate the teaching, suggestion, or motivation (TSM) test from the determination of obviousness, but rather merely opposed "a formalistic conception of the words teaching, suggestion, and motivation, or … overemphasis on the importance of published articles and the explicit content of issued patents." *KSR International Col. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As the Federal Circuit has subsequently explained:

> *[A] flexible TSM test remains the primary guarantor against a non-statutory hindsight analysis*…. The TSM test, flexibly applied, merely assures that the obviousness test proceeds on the basis of *evidence* – teachings, suggestions (a

> tellingly broad term), or motivations (an equally broad term) – that arise before the time of invention as the statute requires.

Ortho-McNeil Pharmaceutical v. Mylan, 2007-1223, *11 (Fed. Cir. Mar. 31, 2008) (emphasis added). Thus, to establish a *prima facie* case of obviousness the Examiner must show *evidence* of teaching, suggestion, or motivation to make the proposed combination of references that arose before the time of invention. Such a showing is required to guard against allegations of obviousness that are actually derived from impermissible hindsight.

Malmonge in view of Slivka, Pissis and Young

As previously indicated, claims 8-9 and 12-14 are rejected under 35 U.S.C. §103(a) as being obvious over Malmonge in view of Slivka, Pissis and Young (previously cited).

Malmonge describes a copolymer of HEMA and acrylic acid (AA) as artificial cartilage material. [Huyghe Declaration, paragraph 5]. The acrylic acid ionizes into acrylate and Na^+, resulting in swelling of the HEMA-AA copolymer and improvement of the compressive strength of the cartilage material. [Huyghe Declaration, paragraph 5]. The Examples describe the presence of ionized groups in the hydrogel at a concentration of 1.8 and 3.6% (m/m). Unlike the present invention, Malmonge does not teach the presence of relatively large fibres in the polymer gel which provide adequate strength and increased mechanical properties as required by the claimed invention. [Huyghe Declaration, paragraph 9].

Slivka describe scaffolds for articular cartilage repair, using biodegradable materials. The sole purpose of Slivka is providing a gel-like matrix (but certainly not a hydrogel) to disperse fibres, which matrix is subsequently dried under vacuum to obtain a highly porous scaffold that is bio-resorbed/degraded upon the build-up of natural cartilage (page 770, par. 2). As such, this document is not concerned with providing materials for use as cartilage substitute, let alone with the swellability properties in water/salt surroundings and the load-bearing capacity of a swollen hydrogel and there would be a lack of motivation to combine the teachings of Slivka (scaffolds for atricular cartilage repair) with the artificial cartilage material (a copolymer of HEMA and acrylic acid (AA)) of Malmonge. In fact, as Slivka is concerned with a biodegradable scaffold for natural cartilage build-up, therefore, this document teaches away from the synthetic polyurethane fibres exemplified in the claimed invention (page 768, pars. 2 and 3).

Pissis is directed toward the dielectric and water sorption properties of poly(hydroxyethyl acrylate) (pHEA) gel reinforced with Nylon nanoparticles. (See Title and first sentence of Introduction). [Huyghe Declaration, paragraph 6]. The fourth-last sentence of the introduction of Pissis teaches "Nylon particles in the scale of nanometers" [emphasis added]. There is no teaching or suggestion in Pissis of the use of millimeter or greater sized fibres, as this reference never contemplates improving the strength or durability of the gel. [Huyghe Declaration, paragraph 6]. Additionally, "the maximum weight percentage of nanoparticles in the hydrogel that could be thus obtained was 10%". Therefore, the claimed fibre having a length of at least a millimeter would not be obvious in view of the teachings of Pissis directed toward a nanoparticle reinforced gel, wherein the loaded nanoparticles are less 10%. Additionally, one skilled in the art would not be motivated to combine the teachings of Pissis (i.e., a gel reinforced with < 10% of nanoparticles) with the teachings of Slivka (scaffolds for atricular cartilage repair) and the artificial cartilage material (a copolymer of HEMA and acrylic acid (AA)) of Malmonge.

Young is an artificial skin substitute for wound dressing characterized as ultrathin (0.23nm) and containing very small amounts of fibre (<1.66%wt%). [Huyghe Declaration, paragraph 7]. Young solely discloses smooth, essentially two-dimensional ultrathing woven or knitted hydrogels, for which elastic strain rather than compressive strength is a prerequisite. [Huyghe Declaration, paragraph 9].

Young does not account for the teachings of Malmonge, Slivka and Pissis. Particularly the combination of Malmonge, Slivka, Pissis and Young does not teach or suggest the claimed material for cartilage-like material substitution, comprising a fibre-reinforced polymerized hydrogel, wherein said polymerized hydrogel contains 10-70% (m/m) swellable fibres (based on the dry matter), wherein the length of the fibres is at least a millimeter, and wherein 1-5% (m/m) (based on the dry matter) of a substance that contains ionized groups has been added to said polymerized hydrogel and, wherein said hydrogel comprises at least one monomer solution.

Finally, we disagree with the Examiner that we "argue elements that are not instantly claimed", particularly durability and improved toughness. Properties such as durability and improved toughness are the consequence of the features comprised in the claims, and part of

the problem solved by the claims.

Furthermore, the swellability of the fibres in the transverse polymerized hydrogel is explicitly claimed. Such fibres are considered in the art not to be hydrophilic. However, after sucking up of the monomers followed by transverse polymerization to form the fibre-reinforced hydrogel according to the invention, the fibres surprisingly obtain hydrophilic properties while being robustly bound to the matrix (cf. par. 6 of the US publication).

Applicants assert that the combination of Malmonge (hydrogel), Slivka (natural cartilage), Pissis (nanoparticles) and Young (thin fibres) would not teach or suggest the claimed cartilage like material. Therefore, Malmonge in view of Slivka, Pissis and Young would not render the claimed cartilage-like material obvious. For the foregoing reasons, withdrawal of the rejection and reconsideration of claims 8-9 and 12-14 are respectfully requested.

Malmonge in view of Slivka, Pissis, Young and Kou

Claims 8 and 10-11 are rejected under 35 U.S.C. §103(a) as being unpatentable over Malmonge in view of Slivka, Pissis and Young as applied to claims 8-9 and 12-14 above, and further in view of Kou (previously cited).

The Examiner characterizes Malmonge, Slivka, Pissis, and Young as above. The Examiner contends that these references do not teach the use of methacrylic acid (MA) in the hydrogel. The Examiner states that this deficiency is satisfied by Kou. The Examiner then concludes that it would have been obvious to substitute modified hydrogel of the Malmonge-Pissis combination with that taught by Kou.

Applicants respectfully traverse the rejection. As explained in detail above, the combination of Malmonge, Slivka, Pissis and Young does not result in Applicants' currently claimed invention of a fibre-reinforced hydrogel comprising a concentration of 10-70% (m/m) fibres with a length of at least a millimeter. Kou does not resolve these deficiencies. Kou describes drug release from methacrylate-methacrylic acid polymer hydrogels. [Huyghe Declaration, paragraph 11]. There is no teaching or suggestion in Kou of the use of long fibres for the improvement of strength and durability in hydrogel compositions. [Huyghe Declaration, paragraph 11]. Kou does not address the problem of improving the toughness of such gels, let alone suggest reinforcement with long fibres for solving this problem. [Huyghe Declaration, paragraph 11]. Therefore, Kou does not account for the deficiencies of the teachings of

Malmonge, Pissis, Slivka and Young. [Huyghe Declaration, paragraph 13]. As such, the present invention is not obvious over Malmonge in view of Pissis, Slivka, Young and Kou. Applicants respectfully request withdrawal of the rejection and reconsideration of claims 8 and 10-11.

Conclusion

Applicants respectfully request reconsideration and submit that all claims are in condition for allowance. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel at the number listed below to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,

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